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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	:	Chapter 11
PURDUE PHARMA L.P., *et al.*,	:	Case No. 19-23649 (RDD)
Debtors.	:	(Jointly Administered)

RESPONSE OF COLLEGIUM PHARMACEUTICAL, INC. TO DEBTORS' MOTION FOR ORDER MODIFYING THE AUTOMATIC STAY TO PERMIT THE DEBTORS TO PROSECUTE CERTAIN PENDING PATENT LITIGATION

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Collegium Pharmaceutical, Inc. ("**Collegium**"), hereby submits this response to the Debtors' Motion for Order Modifying the Automatic Stay to Permit the Debtors to Prosecute Certain Pending Patent Litigation (the "**Motion**"), filed by the above-captioned debtors (the "**Debtors**") of these chapter 11 cases (the "**Bankruptcy Cases**") on July 2, 2020 [Docket No. 1328].[1] In support thereof, Collegium respectfully states:

PRELIMINARY STATEMENT

Prior to the Bankruptcy Cases, the Debtors commenced patent infringement lawsuits against Collegium (the "**Infringement Action**"), asserting that Collegium's New Drug Application for its Xtampza® ER product ("**Xtampza**") infringed on certain of the Debtors' patents, including U.S. Patent No. 9,693,961 ("**the '961 Patent**"). Shortly after the Debtors asserted claims of infringement of the '961 patent in the Infringement Action, Collegium filed a petition for Post Grant Review before the Patent Trial and Appeal Board (the "**PTAB**"), seeking a determination that the '961 patent was invalid (the "**PTAB Action**"). The PTAB concluded the '961 patent is likely invalid and instituted the Post Grant Review proceedings for a trial of the invalidity issue. *See* Exhibit A (PTAB Institution Decision) to Request for Judicial Notice.

Following a Patent Office trial on invalidity, and two weeks before the PTAB was required to issue its determination as to the validity of the '961 Patent, the Debtors filed the Bankruptcy Cases which stayed the Infringement Action and the PTAB Action pursuant to section 362(a) of title 11 of the United States Code, § 101, *et seq.* (the "**Bankruptcy Code**"). While the Debtors seek an order lifting the automatic stay to allow the Debtors to continue the Infringement Action, they failed to reference the related PTAB Action which is necessarily intertwined with the Infringement Action.

[1] On July 14, 2020, the Debtors agreed to an extension of the last date for Collegium to respond to the Motion, from July 16, 2020, to, and including, July 20, 2020.

To avoid the filing of this Response, Collegium contacted the Debtors to request that they stipulate to lifting the automatic stay as to the PTAB Action in addition to the Infringement Action. The Debtors indicated that they have no objection to lifting the stay in the PTAB action, but only to the extent that it does not prejudice the Debtors' novel argument, which they have now raised for the first time, that the PTAB Action "no longer exists." The Debtors posit that the automatic stay destroyed the PTAB action because the PTAB observed the automatic stay and did not issue a determination within what would otherwise have been the statutory deadline set forth under 35 U.S.C. § 326(a)(11), a deadline that would have passed (but for the automatic stay) after the Debtors filed the Bankruptcy Cases.

Collegium acknowledges that the stay can be lifted without the Debtors' waiver of such arguments, but notes that the Debtors' arguments are meritless and antithetical to the very nature of the automatic stay. Moreover, nothing in the statutes governing post grant reviews before the PTAB provides that the PTAB Action ceases to exist if the PTAB does not render its determination by the statutory deadline. Rather, if the deadline had not been automatically tolled by the automatic stay (which it was), the parties may use court process to compel the PTAB to act on any missed deadline. *See Forrest Guardians v. Babbitt,* 174 F.3d 1178 (10th Cir. 1998). Collegium is confident that the PTAB has authority, jurisdiction and will act if the stay is lifted on the PTAB Action.

Collegium proposes that it makes sense for both of the related matters—the Infringement Action and the PTAB Action—to either remain stayed or to go forward. It would be inefficient for the Infringement Action to go forward without the PTAB Action because the PTAB Action will likely be decided in a matter of days after the stay is lifted and may render much of the

Infringement Action moot. On this point, Collegium believes that the Debtors, the Official Committee of Unsecured Creditors appointed in these cases, and Collegium agree.

With respect to the effect of the automatic stay on the PTAB's continuing jurisdiction and authority, Collegium respectfully notes that the question of the PTAB's authority and jurisdiction are matters to be determined by the PTAB. However, to the extent that the Court intends to comment on such issues, it must find that the Debtors' arguments are misplaced and without merit by virtue of the Bankruptcy Code. The automatic stay, which shields the estate from the costs and demands of continuing litigation, cannot also be a sword used by the Debtors to defeat non-debtor litigants. *See, e.g.*, *In re Briarpatch Film Corp.*, 281 B.R. 820 (Bankr. S.D.N.Y. 2002). To the contrary, courts regularly interpret the automatic stay to preserve and protect the rights of non-debtor parties to the stayed litigation, including the automatic extension of statutory deadlines. *Int'l Distribution Centers v. Walsh Trucking Co.*, 62 B.R. 723 (S.D.N.Y. 1986).

Collegium respectfully requests that the Court deny the Motion, or, in the alternative, modify the automatic stay to permit both the Infringement Action and the PTAB Action to proceed.[2]

STATEMENT OF FACTS

1. On September 21, 2017, debtors Purdue Phama, L.P., Purdue Pharmaceuticals, L.P., and P.F. Laboratories, Inc. filed a complaint in the United States District Court for the District of Massachusetts (the "**District Court**"), alleging that Collegium's New Drug Application for its Xtampza product infringed on the Debtors' '961 Patent, thereby commencing the Infringement Action.

[2] Collegium maintains that the Court may make conditions to the modification of the stay based on Debtors' Motion, but out of an abundance of caution, Collegium has filed a Motion to lift the stay, and sought an Order Shortening Time, with respect to the PTAB Action.

2. On December 13, 2017, the District Court consolidated the Infringement Action into the lead action where the Debtors had asserted other patents-in-suit against the Collegium. The consolidated action is styled *Purdue Pharma, L.P., et al. v. Collegium Pharm., Inc.*, Case No. 1:15-cv-13099-FDS.

3. On March 13, 2018, Collegium filed a petition for Post Grant Review of the '961 Patent with the PTAB, commencing the PTAB Action. The PTAB Action is styled *Collegium Pharm., Inc.* v. *Purdue Pharma, L.P. et al.*, Case No. PGR2018-00048.

4. On October 3, 2018, Collegium moved to stay the Infringement Action in view of the related PTAB proceedings related to the '961 Patent. The court took no further action with respect to the '961 Patent and did not set any schedule for proceedings on the '961 Patent following Collegium's motion, allowing the PTAB to complete the trial of the validity of the '961 Patent.

5. On October 4, 2018, the PTAB issued its decision finding that the '961 Patent is eligible for post-grant review, and that Collegium had demonstrated that the '961 Patent was likely unpatentable based on the lack of written description and anticipation grounds set forth in the Petition (the "**Oct. 4 Decision**"). A true and correct copy of the Oct. 4 Decision is attached as Exhibit "A" to the annexed Request for Judicial Notice.

6. Pursuant to 35 U.S.C. § 326(a)(11), the Oct. 4 Decision triggered a one-year deadline for the PTAB to issue its Final Written Decision (i.e. October 4, 2019) (the "**Statutory Deadline**").

7. On September 15, 2019, the Debtors filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code, thereby commencing the Bankruptcy Cases.

8. On September 24, 2019, the Debtors filed a *Notice of Bankruptcy and Imposition of Automatic Stay* in the PTAB Action alerting the PTAB that the PTAB Action was stayed pursuant to section 362(a) of the Bankruptcy Code (the "**PTAB Stay Notice**"). A true and correct copy of the PTAB Stay Notice is attached as Exhibit "B" to the annexed Request for Judicial Notice.

9. On October 2, 2019—two days before the PTAB was required under 35 U.S.C. § 326(a)(11) to render its decision as to the validity of the '961 Patent—the PTAB entered its Order recognizing that the PTAB Action was subject to the automatic stay (the "**PTAB Stay Order**"). A true and correct copy of the PTAB Stay Order is attached as Exhibit "C" to the annexed Request for Judicial Notice.

10. On July 2, 2020, the Debtors filed their Motion seeking relief from the automatic stay to permit the District Court Infringement Action (but not the PTAB Action) to proceed.

11. On July 14, 2020, in an effort to avoid filing a response, Collegium contacted the Debtors to request that they stipulate to lifting the automatic stay as to the PTAB Action in addition to the Infringement Action. *See* Para. 3 to Declaration of Oren Langer, annexed herewith (the "**Langer Declaration**").

12. The Debtors indicated that they are not opposed to Collegium's request, but want to preserve the argument, that they raised for the first time, that the PTAB action "no longer exists" because the PTAB observed the automatic stay and did not issue a final written decision as to the validity of the '961 Patent within what would have been, but for the automatic stay, the Statutory Deadline. *See* Para. 4 to Langer Declaration.

ARGUMENT

A. Cause Does Not Exist to Lift the Automatic Stay Unless the Stay is Lifted as to the PTAB Action.

The Debtors assert that lifting the automatic stay will: (i) serve judicial economy by resulting in a full resolution of the dispute; (ii) not interfere with the Bankruptcy Cases; and (iii) not result in prejudice to any party. *See* Motion, at ¶¶ 13-17. An analysis of each of these factors demonstrates that lifting the automatic stay only serves the interests of the Estate if the stay is lifted as to both the Infringement Action and the PTAB Action. Lifting the stay as to only the Infringement Action can only lead to a waste of Estate resources because the Infringement Action may later become moot when the stay is lifted and the PTAB rules.

1. Lifting the Stay on Both the Infringement Action and The PTAB Action Serves Judicial Economy.

On the Petition Date, the PTAB Action was fully briefed, argued and only days away from the deadline by which the PTAB was scheduled to submit its final decision as to the validity of the ’961 Patent. The Infringement Action, on the other hand, is still in its early discovery stage. Lifting the automatic stay to permit the Infringement Action to proceed, but not the PTAB Action, does not promote judicial economy and will not lead to a full resolution of the Parties’ dispute.

The very purpose of the PTAB Action is to make the Infringement Action more efficient. Seeking an invalidity ruling from the PTAB presents an accused infringer with a speedier alternative than district court litigation to determine if a patent is invalid. Indeed, Congress specifically created the PTAB with the intention that the PTAB’s specialized expertise in the evaluation of patents would avoid wasteful and duplicative proceedings in the District Court, and the judicial economy served by the PTAB process has been acknowledged by District Courts as the basis for staying patent infringement actions where a PTAB proceeding is pending. *See*

Personalweb Technologies, LLC v. Google Inc., No. 5:13–CV–01317–EJD, 2014 WL 4100743, at *5 (N.D. Cal. Aug. 20, 2014) ("Indeed, allowing [patent] invalidity arguments to be determined once, employing the specialized expertise of the PTAB, produces the exact results—avoiding duplicative costs and efforts and averting the possibility of inconsistent judgments—intended by the AIA and previous procedures.").

In the present matter, the PTAB is likely prepared to issue a ruling within days of the stay being lifted. Accordingly, lifting the stay as to the Infringement Action alone will impede judicial economy by depriving the Parties of the benefit of the forthcoming PTAB decision. The PTAB decision will narrow the issues presented in the Infringement Action by resolving the critical issue of the validity of the '961 Patent. The judicial economy served by the PTAB has been acknowledged by courts as a basis for staying the very type of patent infringement litigation that the Debtors seek to continue when a related PTAB proceeding is pending. *See Personalweb*, 2014 WL 4100743, at *5.

2. Lifting the Stay on Both the Infringement Action and The PTAB Action Does Not Interfere with the Bankruptcy Cases.

The Debtors assert that granting relief from the stay, solely as to the Infringement Action, will not interfere with the Bankruptcy Cases, on the basis that the Debtors have ample cash on hand to fund the litigation. Although the Debtors may have sufficient assets to fund the Infringement Action, the Debtors have a fiduciary obligation to their creditors and stakeholders to use those assets as efficiently as practicable. The forthcoming PTAB decision, which will narrow the issues in the Infringement Action, will permit the Debtors to use their funds more efficiently and avoid superfluous expenditure on issues that have already been fully briefed and heard with the PTAB. Thus, lifting the stay as to the Infringement Action, but not the PTAB Action, plainly interferes with the Debtors' efficient use of their assets.

3. Lifting the Stay on Both the Infringement Action and The PTAB Action Will Not Prejudice Any Party.

The Debtors' election to seek relief from the automatic stay as to the Infringement Action, but not the PTAB Action, is prejudicial to creditors of the Estate because it promotes the inefficient use of Estate funds. The PTAB's decision is expected almost immediately. If the '961 Patent is invalidated by the PTAB, it would be a waste of time and money for the Parties' litigation regarding the '961 patent to continue. Conversely, not lifting the stay to permit the PTAB Action to proceed, while allowing the Infringement Action to proceed, will unduly delay the resolution of a key issue in the matter—the validity of the '961 Patent—and will result in significantly greater expense to the Debtors and Collegium.

4. All Factors Weigh in Favor of Lifting the Stay for Both Actions.

Based on the above, the "balance of harm" favors denial of the Debtors' request to lift the stay as to the Infringement Action unless the stay is also lifted as to the PTAB Action. Lifting the stay as to only the Infringement Action will be inefficient and expensive. Conversely, lifting the stay as to the PTAB Action will benefit the Debtors and Collegium with a decision that will narrow the issues of the Infringement Action. Additionally, several additional factors set forth in the Second Circuit's decision in *In re Sommax Industries, Inc.*, 907 F.2d 1280 (2d Cir. 1990), are present here, including: (i) the presence of a specialized tribunal—the PTAB—with the necessary expertise to resolve the PTAB Action; and (ii) the "readiness of trial" in the PTAB Action (which is fully briefed and heard, and awaiting announcement of the decision by the PTAB), as opposed the Infringement Action, which is still in its early discovery phase.

In sum, lifting the automatic stay only serves the interests of the Estate and its creditors if the stay is lifted as to both the Infringement Action and the PTAB Action.

B. The Debtors' Arguments as to the Expiration of the Statutory Deadline are Without Merit.

Despite the clear efficiencies of lifting the stay as to the PTAB Action, the Debtors have asserted that the automatic stay has divested the PTAB of jurisdiction because the PTAB's statutory deadline expired while the PTAB action was stayed. The Debtors' arguments are without merit, are antithetical to the nature of the automatic stay and constitute an improper attempt at forum-shopping, which is not permitted under the Bankruptcy Code. *Matter of U.S. Brass Corp.*, 110 F.3d 1261, 1265 (7th Cir. 1997) ("The use of the Bankruptcy Code to obtain a favorable forum should not be encouraged."); *In re Borgini*, 2005 WL 2205714, at *3 (Bankr. C.D. Ill. 2005) (same).

As an initial matter, the issue of whether the automatic stay divested the PTAB of jurisdiction is a matter for the PTAB to decide. The notion that the stay, or a passing deadline, would divest a body of authority or jurisdiction is not supported by law. As a general rule, if an administrative body, such as the PTAB, fails to render a timely decision, the proper course of action is for parties to compel the agency to act. *Forrest Guardians v. Babbitt*, 174 F.3d 1178 (10th Cir. 1998) (holding that when an agency fails to act by a "statutorily imposed absolute deadline," under the Administrative Procedure Act, the action has been "unlawfully withheld" and the court has no choice but to compel the agency to act).[3] Whether jurisdiction exists at the PTAB is solely a decision for the PTAB to make; Collegium is confident that the PTAB will find that any period in which it was required to act has been tolled and that in any event, the expiration of any such period would not divest the PTAB of jurisdiction or authority.

[3] To be clear, Collegium does not contend that, by obtaining relief from stay as to the PTAB Action, the Debtors waive their right to argue that the PTAB lacks jurisdiction to render its decision.

From a bankruptcy law perspective, it should be clear that any applicable statutory deadline in a stayed proceeding is automatically extended pursuant to sections 108(c) and 362(a) of the Bankruptcy Code. Section 362(a)(1) prevents the "commencement or continuation… of a judicial, administrative, or other action or proceeding against the debtor." 11 U.S.C. § 362(a). The automatic stay suspends judicial proceedings against the debtor in their entirety—including any and all deadlines in the proceeding. *See Bank of America, N.A. v. Johnson*, 479 B.R. 159 (Bankr. N.D. Ga. 2012) (holding that the automatic stay suspended the obligation of the debtor to file an answer because "the automatic stay means nothing if it does not operate to stay the proceeding **in its entirety**.") (emphasis added). Section 108(c) provides that "if applicable nonbankruptcy law [or] an order entered in a nonbankruptcy proceeding... fixes a period for… continuing a civil action in a court other than a bankruptcy court on a claim against the debtor… then such period does not expire until the later of the end of such period… or 30 days after the notice of the termination or expiration of the stay." 11 U.S.C. § 108(c). Several Courts hold that sections 108(c) and 362(a) operate to toll and extend all deadlines in all matters subject to the stay, whether imposed by appropriately promulgated rules, statute or Court order.

For example, in the decision, *In re Hoffinger Industries, Inc.*, 329 F.3d 948 (8th Cir. 2003), the Eighth Circuit Court of Appeals held that the statutory deadline for the parties to file an appeal was automatically tolled pursuant to sections 362(a) and 108(c). In doing so, the Court reasoned:

> [W]e note the obvious fit between the provisions in section 362(a)(1) regarding the application of the automatic stay to 'continuation' of a 'judicial proceeding against the debtor' and the language in section 108(c) regarding the extension of applicable nonbankruptcy deadlines relevant to 'continuing a civil action… against the debtor' until after the stay has expired or terminated… section 108(c) will be applicable if the stay terminates.").

Id. at 952, citing *Collier on Bankruptcy* ¶ 108.03[2], at 108-10 (15th ed.); *see also In re Shamus Holdings, LLC*, 642 F.3d 263 (1st Cir. 2011) (in which the First Circuit Court of Appeals held that the statutory period for a mortgagee to record an extension of a mortgage was automatically extended pursuant to section 108(c) of the Bankruptcy Code).

Based on the above, sections 362(a) and 108(c) support the assertion that all deadlines set forth in the PTAB Action—including the Statutory Deadline for the PTAB to render its decision—are automatically extended as a result of the Debtors' bankruptcy filing. Indeed, the argument set forth by the Debtors—that only certain dates and deadlines in a stayed action are suspended—would be impossible and unnecessary. Instead, the automatic stay must be interpreted as broadly as it is written to suspend all actions it applies to, which necessarily encompasses the suspension of deadlines and requirements for parties (and the court or agency in which the stayed action is pending) to act.

C. The Debtors' Use of the Automatic Stay as a Sword is Improper.

It is clear that, by seeking relief from the automatic stay to permit the Infringement Action, but not the PTAB Action, to proceed, the Debtors are plainly using the automatic stay as a tool to achieve a litigation advantage over Collegium, an increasingly bothersome competitor of the Debtors. The automatic stay, however, is intended to shield the bankruptcy estate from the costs and demands of continuing litigation so that the debtor is able to focus on managing issues of the bankruptcy estate in an efficient manner—not to be used as a sword by debtors to obtain a litigation advantage against non-debtor parties. *Int'l Distribution Centers v. Walsh Trucking Co.*, 62 B.R. 723 (S.D.N.Y. 1986) ("[a]lthough section 362 is a shield to protect the debtor to provide for a fresh start, the automatic stay was not intended by Congress to be used as a sword."); *In re Briarpatch Film Corp.*, 281 B.R. 820 (Bankr. S.D.N.Y. 2002) ("it has been often stated that the automatic stay is a shield, not a sword"). Accordingly, Courts routinely reject efforts by debtors

to use the automatic stay as a tool to obtain a litigation advantage. *See Matter of U.S. Brass Corp.*, 110 F.3d 1261, 1265 (7th Cir. 1997) ("The use of the Bankruptcy Code to obtain a favorable forum should not be encouraged."); *In re Borgini*, 2005 WL 2205714, at *3 (Bankr. C.D. Ill. 2005) (same); *In re Briarpatch Film Corp.*, 281 B.R. 820 (Bankr. S.D.N.Y. 2002) (the automatic stay cannot "be used to prevent the entry of judgment against the debtor on a lawsuit in which its rights have been fully litigated."); *In re Collins*, 250 B.R. 645, 663 (Bankr. N.D. Ill. 2000) ("[Debtor] did not merely invoke the shield of the automatic stay; he converted it to a sword for the sole purpose of" frustrating an opposing litigant, which was improper).

The Debtors' attempt to use the automatic stay as a shield to prevent the PTAB from rendering its decision, while simultaneously using it as a sword to pursue the Infringement Action as its exclusive forum, constitutes an improper abuse of the automatic stay and should be rejected.

CONCLUSION

WHEREFORE, Collegium respectfully requests that the Court deny the Motion, or, in the alternative, modify the automatic stay to permit both the Infringement Action and the PTAB Action to proceed.

Dated: July 20, 2020
Los Angeles, California

ROBINS KAPLAN LLP

By: /s/ Scott F. Gautier

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Counsel to Collegium Pharmaceutical, Inc.

DECLARATION OF OREN LANGER

I, Oren D. Langer, hereby declare:

1. I am a partner with the law firm of Robins Kaplan LLP, counsel to Collegium Pharmaceutical, Inc. ("**Collegium**") in the above-captioned bankruptcy case styled *In re Purdue Pharma L.P., et al.*, case no. 19-23649 RDD. I submit this declaration in support of the *Response of Collegium Pharmaceutical, Inc. to Debtors' Motion for Order Modifying the Automatic Stay to Permit the Debtors to Prosecute Certain Pending Patent Litigation* (the "**Response**"). Unless otherwise defined herein, all capitalized terms shall have the meanings ascribed to them in the Response, as applicable.

2. Unless otherwise stated, I have personal knowledge of the matters set forth herein and, if called as a witness, could and would competently testify to the same.

3. On July 2, 2020, the above-captioned debtors (the "**Debtors**") filed their *Motion for Order Modifying the Automatic Stay to Permit the Debtors to Prosecute Certain Pending Patent Litigation* (the "**Motion**"), seeking an order lifting the automatic stay as to patent litigation against Collegium currently pending before the United States District Court for the District of Massachusetts (the "**Infringement Action**"), but not the Post Grant Review of the '961 Patent currently before the Patent Trial and Appeal Board (the "**PTAB Action**").

4. On July 14, 2020, in an effort to avoid filing a response to the Motion, counsel for Collegium met and conferred with counsel for Debtors to request that the parties stipulate to lifting the automatic stay as to the PTAB Action in addition to the Infringement Action. I was on that call.

5. Debtors' counsel indicated that they were not opposed to Collegium's request, but wanted to preserve the argument, raised for the first time on the July 14, 2020 telephone call, that the PTAB action "no longer exists" because the PTAB did not issue a final written decision as to the validity of the '961 Patent within what would have been, but for the automatic stay, the Statutory Deadline.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 20th day of July, 2020 at New York, New York.

Oren Langer

REQUEST FOR JUDICIAL NOTICE

Collegium Pharmaceutical, Inc. ("**Collegium**") hereby requests, pursuant to Federal Rule of Evidence 201, that this Court, in its consideration of Collegium's *Response to the Debtors' Motion for Order Modifying the Automatic Stay to Permit the Debtors to Prosecute Certain Pending Patent Litigation* (the "**Response**"), take judicial notice of the information contained in the exhibits attached hereto.[4]

1. The October 4, 2018, decision issued by the PTAB finding that the '961 Patent is eligible for post-grant review, a true and correct copy of which is attached hereto as Exhibit "A."

2. The *Notice of Bankruptcy and Imposition of Automatic Stay* filed by the Debtors on September 24, 2019, in the PTAB Action, a true and correct copy of which is attached hereto as Exhibit "B."

3. The Order entered by the PTAB on October 2, 2019 recognizing that the PTAB Action was subject to the automatic stay, a true and correct copy of which is attached hereto as Exhibit "C."

Dated: July 20, 2020
Los Angeles, California

ROBINS KAPLAN LLP

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Counsel to Collegium Pharmaceutical, Inc.

[4] Unless otherwise provided, capitalized terms used herein shall have the same meanings as set forth in the Response.

Exhibit A

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Paper No. 18
Entered: October 4, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COLLEGIUM PHARMACEUTICAL, INC.,
Petitioner,

v.

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P.,
AND THE P.F. LABORATORIES INC.,
Patent Owner.

Case PGR2018-00048
Patent 9,693,961 B2

Before CHRISTOPHER G. PAULRAJ, JACQUELINE T. HARLOW, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

DECISION
Instituting Post-Grant Review of Claims 1–17
35 U.S.C. § 324 and 37 C.F.R. § 42.208

I. INTRODUCTION

Collegium Pharmaceutical, Inc. ("Petitioner") filed a Petition requesting post-grant review of claims 1–17 of U.S. Patent No. 9,693,961 B2 (Ex. 1001, "the '961 patent"). Paper 4 ("Pet."). Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 13 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 324.

To institute a post-grant review, we must determine whether the information presented in the Petition, "if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." 35 U.S.C. § 324(a). Upon consideration of the Petition and the Preliminary Response, for the reasons set forth below, we determine that the evidence and arguments presented in the Petition are sufficient to satisfy the "more likely than not" standard regarding the asserted unpatentability of claims 1–17 in the '961 patent. Therefore, we authorize a post-grant review to be instituted as to those claims.

Our determinations at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to patentability of claims for which post-grant review is instituted. Our final decision will be based on the full record developed during trial.

Taking account of the information presented in the Petition and Preliminary Response, we determine that the Petition shows sufficiently the following facts for the purposes of trial institution.

A. Related Proceedings

Patent Owner asserted the '961 patent against Petitioner in a civil action in the United States District Court for the District of Massachusetts captioned as *Purdue Pharma L.P. et al. v. Collegium Pharmaceutical, Inc.*, 1-17-cv-11814 on September 21, 2017. Pet. 4. Civil Action No. 1-17-cv-11814 was consolidated on December 13, 2017 for case management and discovery purposes, with pending litigation captioned as *Purdue Pharma L.P. et al. v. Collegium Pharmaceutical, Inc.*, 1-15-cv-13099 (D. Mass., filed Aug. 6, 2015). Pet. 4.

Other members of the '961 patent's family have also been involved in litigation. The '961 patent issued from the same non-provisional application, No. 10/214,412, as U.S. Patent Nos. 8,337,888 (the "'888 patent"); 9,060,976 (the "'976 patent"); and 9,034,376 (the "'376 patent"). Some of the '888 patent's claims were previously found invalid for obviousness and indefiniteness. *See In re OxyContin Antitrust Litig.*, No. 04-Md-1603, 2015 U.S. Dist. LEXIS 45967, at *53 (S.D.N.Y. Apr 8, 2015), *aff'd*, No. 2015-1654 (Fed. Cir. Apr. 8, 2016). Additionally, both the '976 patent and the '376 patent have previously been the subject of *inter partes* review proceedings resulting in final written decisions of unpatentability. IPR2016-01027; IPR2016-01028; IPR2016-01412; IPR2016-01413.

B. The '961 Patent

The '961 patent, titled "Pharmaceutical Formulation Containing Gelling Agent," discloses controlled release oral dosage forms subject to less parenteral, intranasal, or oral abuse than other dosage forms. *See, e.g.*, Ex. 1001, Abstract; 2:31–55. It issued from an application (No. 15/015,722) filed February 4, 2016, but claims priority through a series of continuations

to a provisional application (No. 60/310,534, Ex. 1005) filed August 6, 2001. *Id.* at (60), (63).

The controlled release oral dosage forms of the '961 patent comprise a therapeutically effective amount of a drug susceptible to abuse together with one or more pharmaceutically acceptable excipients, including a gelling agent in an effective amount to impart a viscosity unsuitable for administration via parenteral and nasal routes when the dosage is crushed and mixed with an aqueous liquid. *Id.* at 2:31–55.

The specification explains that "[o]pioid analgesics are sometimes the subject of abuse," and oral opioid formulations are often abused by extracting the opioid from the dosage form and injecting it, or by crushing the dosage form and administering it orally or nasally. *Id.* at 1:26–40. As recognized in the patent, the prior art describes dosage forms that combine opioid antagonists with opioid agonists to deter parenteral abuse of opioid agonists. *Id.* at 1:42–2:12. The prior art further describes narcotic drug addiction therapies "formulated to prevent injection abuse through concentration of the active component in aqueous solution by incorporating in a solid dosage or tablet form of such drug an ingestible solid having thickening properties which cause rapid increase in viscosity upon concentration of an aqueous solution thereof." *Id.* at 2:13–20. In spite of the advancements discussed in the prior art, "there still exists a need for a safe and effective treatment of pain with opioid analgesic dosage forms which are less subject to abuse than current therapies." *Id.* at 2:21–24.

The invention claimed in the '961 patent addresses this need by providing oral dosage forms of an opioid analgesic subject to less parenteral abuse, less intranasal abuse, less oral abuse, and less diversion than other

dosage forms; by providing "a method of treating pain in human patients with an oral dosage form of an opioid analgesic while reducing the abuse potential of the dosage form"; and by providing a "method of manufacturing an oral dosage form of an opioid analgesic such that it has less abuse potential." *Id.* at 2:31–51. The claimed invention is directed to an oral dosage form comprising an opioid analgesic and at least one aversive agent for reducing abuse. *Id.* at 2:52–55. Aversive agents help to prevent injection, inhalation, and oral abuse by making the dosage form less attractive to a potential abuser. *Id.* at 56–61. Certain embodiments of the invention comprise aversive agents such as bittering agents, irritants, gelling agents, or some combination of the three. *Id.* at 2:62–3:50.

C. Illustrative Claim

Petitioner challenges claims 1–17 of the '961 patent, of which claims 1 and 16 are the only independent claims. Claim 1 recites:

> 1. A method of preparing an abuse deterrent controlled release dosage form comprising:
>
> combining oxycodone or a pharmaceutically acceptable salt thereof as active agent, polyglycolyzed glycerides, a C_{12} to C_{40} fatty acid or a mixture thereof, carnauba wax and beeswax, to form a homogenous mixture, wherein the oxycodone or pharmaceutically acceptable salt thereof is the sole active agent in the dosage form;
>
> preparing particles from the homogenous mixture; and containing the particles in a capsule;
>
> the abuse deterrent dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient, and

> the abuse deterrent dosage form being abuse deterrent when subjected to tampering comprising heating at a temperature greater than about 45° C.

Ex. 1001, 41:37–52. Depending from claim 1, claims 2–15 further set forth the requirements for the particles, the oxycodone or pharmaceutically acceptable salt thereof, the fatty acid, the method of combining the materials in the homogenous mixture, the composition of the homogenous mixture, and size of the particles. *Id.* at 42:1–30. Independent claim 16 is similar to claim 1, except it requires the abuse deterrent dosage form to "hav[e] a viscosity of about 10 cP or more when subjected to tampering comprising heating at a temperature greater than about 45° C." *Id.* at 42:33–49. Depending from claim 16, claim 17 further sets forth the particle size and requires that "the particles have a diameter from about 0.1 mm to about 2.5 mm." *Id.* at 50–51.

D. Asserted Grounds of Unpatentability

Petitioner advances four grounds of unpatentability in relation to claims 1–17 ("the Challenged Claims") in the '961 patent and seeks cancellation of all issued claims. *See* Pet. 3, 6. Petitioner states that the '961

patent is unpatentable for 1) lack of written description; 2) lack of enablement; 3) indefiniteness; and 4) anticipation. *Id.*

Ground	Claims	Statutory Basis
1	1–17	35 U.S.C. § 112 (written description)
2	1–17	35 U.S.C. § 112 (enablement)
3	1–17	35 U.S.C. § 112 (indefiniteness)
4	1–17	35 U.S.C. § 102 (anticipation based on United States Patent Application Publication 2011/0142943 ("the '943 Publication") (Ex. 1046)

Petitioner further relies on the declaration of Walter G. Chambliss, Ph.D. Ex. 1002. In support of its Preliminary Response, Patent Owner relies upon the declaration of Panayiotis P. Constantinides, Ph.D. Ex. 2001.

E. Person of Ordinary Skill in the Art

Petitioner proposes that a person of ordinary skill in the art ("POSA") would possess "a degree in one or more fields of medicine, chemical engineering, chemistry, pharmaceutical science, and/or pharmacology and a number of years of industry training or experience in one or more of those fields." Pet. 21 (citing Ex. 1002 ¶ 82). Petitioner further proposes that "[i]f the degree is a Ph.D[.], then the required industry experience need not be significant, e.g., two years or more, but if the technical degree is a B.S. or M.S., then the industry experience would be more significant, e.g., five years or more." *Id.* (citing Ex. 1002 ¶ 82). Patent Owner does not address the level of ordinary skill in the art in the Preliminary Response.

Petitioner's presently undisputed proposed definition is not inconsistent with the cited prior art, and we adopt it for the purposes of this

Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

II. POST-GRANT REVIEW ELIGIBILITY

A. Legal Standards

Post-grant reviews are available only for patents "described in section 3(n)(1)" of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"). AIA § 6(f)(2)(A); *see Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 13 at 15 (PTAB Sept. 2, 2016). These patents issue from applications "that contain[] or contained at any time . . . a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after" "the expiration of the 18-month period beginning on the date of the enactment of" the AIA. AIA § 3(n)(1). Because the AIA was enacted on September 16, 2011, post-grant reviews are available only for patents that issue from applications that at one point contained at least one claim with an effective filing date of March 16, 2013, or later. *See also* 37 C.F.R. § 42.204(a) (requiring that "petitioner . . . certify that the patent for which review is sought is available for post-grant review").

The effective filing date of an application for a patent on an invention is "the filing date of the earliest application for which the . . . application is entitled, as to such invention, to a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b) or to the benefit of an earlier filing date under section 120, 121, 365(c), or 386(c)." 35 U.S.C. § 100(i)(1)(B). In the event

that the application is not entitled to any earlier filing date or right of priority, the effective filing date is "the actual filing date of the . . . application for the patent containing a claim to the invention." 35 U.S.C. § 100(i)(1)(A). An application may be entitled to the benefit of an earlier filing date if the earlier document provides adequate written description support for the application's claims. The test for written description support is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date" based on an "objective inquiry into the four corners of the specification." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). If this test fails, the application is not entitled to the benefit of the earlier filing date.

The '961 patent was issued on July 4, 2017 from U.S. Application Ser. No. 15/015,722 (the "'722 application"), filed on February 4, 2016. Ex. 1001. The '722 application, through a series of continuation applications, claims benefit of priority of U.S. Provisional Application No. 60/310,534 (the "'534 Provisional Application", Ex. 1005), filed on August 6, 2001. Because it was filed after March 16, 2013, the '722 application is an AIA (first-inventor-to-file) application; but the '534 provisional application and other non-provisional applications with the same disclosures filed before that date are pre-AIA (first-to-invent) applications.

In a post-grant review, as in an *inter partes* review, "the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800

F.3d 1375, 1378 (Fed. Cir. 2015). In determining whether the '961 patent is eligible for post-grant review, we consider the present record in its entirety. *See* 35 U.S.C. § 324 ("The determination by the Director whether to institute a post-grant review under this section shall be final and nonappealable.").

B. Analysis

Petitioner asserts that the '961 patent is eligible for post-grant review because the Challenged Claims are not entitled to an effective filing date earlier than the February 4, 2016 filing date of the '722 application. Pet. 24–26. Petitioner contends that the earlier applications to which the '961 patent claims priority ("Related Applications") do not provide written description support for the Challenged Claims under 35 U.S.C § 112(a) because oxycodone, polyglycolyzed glycerides ("PGGs"), C_{12}–C_{40} fatty acids, carnauba wax, and beeswax (the "Claimed Pharmaceutical Ingredients") are not described together as a combination anywhere in the specification, and the claimed dosage form is the result of impermissible "picking and choosing" from the specification of the '534 Provisional Application. *Id.* at 33–40.

In its Preliminary Response, Patent Owner contends that, "transitional" continuation patents such as the '961 patent are not PGR-eligible. Prelim. Resp. 26–28. We are unpersuaded by this argument. It is well-established by prior Board decisions that a patent claiming the benefit of priority of an application filed before March 16, 2013 must have written description support for the claimed invention in the earlier-filed application in order to avoid PGR-eligibility. *See, e.g.*, *Inguran, LLC d/b/a Sexing Technologies v. Premium Genetics (UK) Ltd.*, PGR2015-00017, Paper 8 at

10–11 (PTAB Dec. 22, 2015); *Arkema Inc. v. Honeywell Int'l Inc.*, PGR2016-00011, Paper 54 at 21–22 (PTAB Aug. 31, 2017).

Patent Owner also relies on the PTO's designation during prosecution of the '722 application patent as a "pre-AIA" application. Prelim. Resp. 29. In particular, Patent Owner points to the office action indicating "No" in the box labeled in the box labeled "AIA (First Inventor to File) Status" and the Examiner's reference to "pre-AIA 35 U.S.C. 103(a)." *Id.* (citing Ex. 2004, 2, 4). Patent Owner contends that the PTO's designation shows that the Examiner "already considered the question of whether the '722 application was an AIA application," and is sufficient to deny institution of post-grant review. *Id.* at 30. Patent Owner cites two prior Board decisions, *Mylan Pharm. Inc. v. Yeda Research & Dev. Co. LTD.*, PGR2016-00010, Paper 9 at 7 (PTAB Aug. 15, 2016) ("*Mylan*") and *Merck Sharp & Dohme Corp. v. Wyeth LLC*, PGR2017-00016, Paper 9 at 14–15 (PTAB Oct. 20, 2017) ("*Merck*"), to assert that "[t]he PTAB has held such a pre-AIA designation to be a relevant factor in determining whether a patent is eligible for PGR." *Id.* at 29.

While we recognize that pre-AIA status designations during prosecution may be considered, that alone is not conclusive. For instance, in *Mylan*, it was noted that the patent examiner substantively considered whether the subject matter in the claims at issue were disclosed by the ancestor application because the examiner initially rejected the claims for obviousness-type double-patenting. PGR2016-00010, Paper 9, at 6–8. In *Merck*, the Board only noted that the designation of pre-AIA status during prosecution was "consistent" with its own determination on the merits that the challenged claims were supported in the priority applications.

PGR2016-00016, Paper 9 at 14. Therefore, contrary to Patent Owner's arguments, we have not treated a pre-AIA designation made during prosecution as dispositive of the issue of whether the challenged patent is PGR eligible. We, therefore, turn to the merits of Petitioner's arguments as to why challenged claims are not entitled to the benefit of an earlier priority application.

With regard to its "picking and choosing" argument, Petitioner contends that although the '534 Provisional Application individually references the Claimed Pharmaceutical Ingredients at various points in the specification, it provides "no teaching or Example demonstrat[ing] that the inventors possessed a method of preparing a capsule dosage form combining" oxycodone, PGG, C_{12} to C_{40} fatty acids, carnauba wax, and beeswax. Pet. 34. In this regard, Petitioner points out that the '534 Provisional Application mentions PGG only once, as an optional surfactant. *Id.* at 35. Petitioner also contends that the '534 Provisional Application lacks an explanation about the steps required to prepare and combine a homogenous mixture of the Claimed Pharmaceutical Ingredients, and provides no example of any dosage form that is abuse deterrent when exposed to tampering at a temperature greater than about 45° C. *Id.* at 36–37; Ex. 1002 ¶¶ 112–114. According to Petitioner, the "lack of teaching is telling, as a POSA would look for these disclosures in the specification given that the claimed pharmaceutical excipients have varied physiochemical properties . . . that play an important role in regulating API [active pharmaceutical ingredient, i.e., oxycodone] release." *Id.* at 36.

Patent Owner contends that the "Matrix Formulations" section of the specification found in the '534 Provisional Application teaches the

combination of the Claimed Pharmaceutical Ingredients. Prelim. Resp. 34. From that section, Patent Owner points to the disclosure that a hydrophobic binder may be selected from "natural and synthetic waxes, ***fatty acids***, fatty alcohols, and mixtures of the same," that "[e]xamples include ***beeswax***, ***carnauba wax***, stearic acid and stearyl alcohol," and "[i]n certain ***preferred*** embodiments, a ***combination*** of two or more hydrophobic binder materials are included in the matrix formulation." *Id.* at 36 (citing Ex. 1001 at 15:64–16:8; Ex. 1005 at 22; Ex. 1006 ¶¶ 97–98). Patent Owner notes that the claimed C_{12}–C_{40} fatty acids are "especially" "[p]referred hydrophobic materials." *Id.* (citing Ex. 1001 at 16:9–13; Ex. 1005 at 22; Ex. 1006 ¶ 99). Additionally, Patent Owner highlights the following sentence from that section as allegedly encompassing all of the claimed excipients:

> In certain embodiments, the hydrophobic binder materials may comprise natural or synthetic ***waxes***, fatty alcohols (such as lauryl, myristyl, stearyl, cetyl or preferably cetostearyl alcohol), ***fatty acids***, including but not limited to ***fatty acid esters, fatty acid glycerides*** (mono-, di-, and tri-glycerides), hydrogenated fats, hydrocarbons, normal waxes, ***stearic acid***, stearyl alcohol and hydrophobic and hydrophilic materials having hydrocarbon backbones.

Id. at 37 (citing Ex. 1001 at 16:23–29; Ex. 1005 at 23; Ex. 1006 ¶ 100).

In addition to the foregoing disclosures, Patent Owner further notes that the specification teaches that "surfactants" may be among the gelling agents used to deter abuse, and that PGGs are specifically identified as an exemplary surfactant. *Id.* at 37–38 (citing Ex. 1001, 7:11–12, 28:36–41; Ex. 1005 at 10, 40; Ex. 1006 ¶¶ 49, 89, 173).

Based on the present record, we find that Petitioner has demonstrated sufficiently that the claimed invention lacks written description support in any of the Related Applications, including the '534 Provisional Application. In particular, we find that the "Matrix Formulations" section, relied upon by Patent Owner, does not adequately describe the Claimed Pharmaceutical Ingredients insofar as that section does not specifically mention that PGGs may be used as a binder material in the formulation. While we recognize that this section mentions other ingredients, namely beeswax, carnauba wax, and C_{12}–C_{40} fatty acids with a particularity that matches the scope of the claims, the present record does not demonstrate that the disclosure of "fatty acid esters" or "fatty acid glycerides" in the same section is sufficient to show that the inventors possessed the concept that PGGs may be used a binder material in the formulation. In this regard, we note that Patent Owner's own expert acknowledges that not all "glycerides" and "fatty acid esters" would qualify as PGGs, which are specific mixtures of fatty acid esters of glycerol (i.e., fatty acid glycerides) and fatty acid esters of polyethylene glycol (PEG). Ex. 2001 ¶¶ 26–27.

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Satisfaction of this standard is fact-intensive and is determined on a case-by-case basis; the Federal Circuit has declined to "set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim." *Ariad Pharm.*, 598 F.3d at 1351. "[A] sufficient

description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350. Further, in "chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application." *In re Smythe*, 480 F.2d 1376, 1383 (CCPA 1973). Thus, while the more generic disclosures of "fatty acid glycerides" or "fatty acid esters" in the Matrix Formulations section might render the use of PGGs obvious, that is insufficient to satisfy the written description requirement. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) ("A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement."). Further evidence will need to be developed during trial in order for us to make a final determination as to whether the disclosure of a genus of "fatty acid glycerides" or "fatty acid esters" would be considered sufficient to show possession of PGGs as part of the Claimed Pharmaceutical Ingredients.

We are also unpersuaded by Patent Owner's reliance on the specification's disclosures regarding "gelling agents" and "surfactants" to satisfy the written description requirement. The specification discloses that gelling agents may include "surfactants" and "mixed surfactant/wetting agent systems," and then later lists PGGs among a list of about 45 other ingredients that may be used as surfactants. Ex. 1005, 10, 40. On the

present record, we find that this "laundry list" disclosure is insufficient to show that the inventors were in possession of a formulation that includes PGG in combination with the other recited Claimed Pharmaceutical Ingredients. The Federal Circuit has held that such laundry list disclosures are insufficient to satisfy the written description requirement when there is no further guidance ("blazemarks") provided about which species or combination of species included as part of the list may be selected to arrive at the claimed invention. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996). Not having specifically named or mentioned the combination in any manner, "one is left to select[] from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made." *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967); *see also Los Angeles Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, 849 F.3d 1049, 1057 (Fed. Cir. 2017) ("To satisfy the written description requirement, the disclosure in each application must 'reasonably convey[ ]' to those skilled in the art that as of the claimed priority date the inventor was in possession of the later claimed subject matter." (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991))).

We have also considered Petitioner's other arguments as to why the Challenged Claims of the '961 patent are not entitled to the benefit of an earlier filing date, including the contention that the inventors were not in possession of the full scope of "abuse deterrent dosage forms," and the argument that the Related Applications do not enable the full scope of the challenged claims. Pet. 28–33, 40–66. On the present record, we are not as

persuaded by these arguments largely for the reasons set forth in Patent Owner's Preliminary Response. Prelim. Resp. 31–33, 43–66. We will reconsider these arguments after further development of the record during trial.

III. ANALYSIS OF ASSERTED GROUNDS

Petitioner asserts that claims 1–17 of the'961 patent are unpatentable based on four separate grounds: 1) lack of written description support; 2) lack of enablement; 3) indefiniteness; and 4) anticipation.

A. Ground 1: Lack of Written Description Support

Petitioner contends that the Challenged Claims are unpatentable for lack of written description for the same reasons it contends the '961 patent is PGR eligible. Pet. 67–68. The specification of the '961 patent has substantially the same disclosures as the specification of the Related Applications (including the '534 Provisional Application) to which the '961 patent claims priority. Having determined that these disclosures in the Related Applications are insufficient to provide written description support for the claimed invention, we also determine that Petitioner has demonstrated more likely than not that the Challenged Claims are unpatentable for the same reasons. Thus, we exercise our discretion and institute post grant review of claims 1–17 challenged under this ground.

B. Ground 2: Lack of Enablement

Additionally, Petitioner contends that the Challenged Claims are unpatentable due to lack of enablement for largely the same reasons it argues for PGR eligibility. Pet. 68–69. Moreover, Petitioner contends that the number of oxycodone APIs and abuse deterrent dosage forms have grown as of the effective filing date, and thus "a POSA would need to experiment

with numerous additional oxycodone APIs and abuse deterrent dosage forms in order to enable the full scope of the Challenged Claims." *Id.* at 68 (citing Ex. 1002 ¶¶ 196, 202, 207). We did not determine that the '961 patent is PGR-eligible on this basis, as noted above.

We are not persuaded that the Challenged Claims are unpatentable for lack of enablement largely for the reasons set forth in Patent Owner's Preliminary Response. Prelim. Resp. 43–66. For instance, in practicing the claimed methods, we find that a POSA would have focused on improving the original OxyContin formulation (which included oxycodone hydrochloride), and would have known to use commercially available and pharmaceutically acceptable grades of PGG, C_{12}–C_{40} fatty acids, and waxes that were known in the prior art. Ex. 2001 ¶¶ 104–113. Furthermore, methods of manufacturing such sustained-release dosage forms (e.g., melt-granulation and melt-extrusion) are identified in the specification and were known in the prior art. Ex. 1001, 17:42–43; Ex. 2001 ¶¶ 36–39. As such, especially when taking into account what was known in the prior art, the present record does not suggest that any experimentation required to arrive at the claimed formulation would have been considered "undue." *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) ("Factors to be considered in determining whether a disclosure would require undue experimentation . . . include . . . the state of the prior art.").

Accordingly, we are not persuaded based on the present record that Petitioner has demonstrated more likely than not that the Challenged Claims are unpatentable for lack of enablement. We will reconsider this unpatentability ground after further development of the record during trial.

C. Ground 3: Indefiniteness

Petitioner contends that the Challenged Claims are indefinite because they result a result—an "abuse deterrent dosage form"—without claiming either the process or pharmaceutical ingredients that produce the result. Pet. 69–70 (citing *Forest Labs., Inc. v. Teva Pharm. USA, Inc.*, 716 F. App'x 987, 996 (Fed. Cir. 2017) (Lourie, concurring)). Patent Owner does not address this ground in its Preliminary Response.

On the present record, we are not persuaded that the claims are indefinite on this basis. The claims define abuse deterrence in terms of when the dosage form is "subjected to tempering comprising heating at a temperature greater than about 45° C." Ex. 1001, 41:50–52. Additionally, the claims and specification identify specific ingredients that can help achieve this abuse deterrence functionality. We find this to be distinguishable from the claims at issue in *Forest Labs*, which were construed to require human study comparisons and found indefinite because the evidence did not establish the particular studies used to make such comparisons. 716 F. App'x. at 994–95. We will reconsider this unpatentability ground after further development of the record during trial.

D. Ground 4: Anticipation

Petitioner contends that the Challenged Claims are anticipated by the '943 Publication (Ex. 1046). Pet. 70–84. The '943 Publication is assigned to Petitioner, and has a publication date of June 16, 2011. As such, it only qualifies as prior art in the event that the '961 patent is not entitled to claim the benefit of an earlier priority date. Petitioner has presented a claim chart to demonstrate how each of the limitations of the Challenged Claims are taught in the '943 Publication. Pet. 72–74, 80–84. Patent Owner does not

dispute these contentions in the Preliminary Response, but instead only argues that the '943 Publication is not prior art. Prelim. Resp. 2

As stated above in our determination that the '961 patent is PGR eligible, we determine on the present record that Petitioner has shown that the challenged claims are not entitled to an earlier priority date, and thus the '943 Publication qualifies as prior art. Based on the present record, we also determine that Petitioner has demonstrated more likely than not that the Challenged Claims are unpatentable based on this anticipation ground.

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner has demonstrated sufficiently that Challenged Claims 1–17 of the '961 patent lack written description support in the '534 Provisional Application or any of the other Related Applications filed before March 16, 2013. Accordingly, we conclude that the '961 patent is eligible for post-grant review. Additionally, we determine that Petitioner has demonstrated that the Challenged Claims are more likely than not unpatentable at least based on the lack of written description and anticipation grounds set forth in the Petition. We determine that these grounds of unpatentability warrant institution of a trial in this PGR proceeding.

Under the Office's Guidance implementing *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018): "[a]t this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." Guidance on the Impact of *SAS* on AIA Trial Proceedings ("Guidance"), available at https://www.uspto.gov/patentsapplication-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (April 26, 2018). Accordingly, we institute trial as to all claims and all grounds presented in the Petition.

V. ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 324, a post grant review of the ’961 patent is instituted as to claims 1–17 based on the unpatentability grounds set forth in the Petition; and

FURTHER ORDERED that a post grant review is commenced on the entry date of this Order, and pursuant to 35 U.S.C. § 324(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

PGR2018-00048
Patent 9,693,961 B2

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Exhibit B

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COLLEGIUM PHARMACEUTICAL, INC.,
Petitioner

v.

PURDUE PHARMA L.P.,
PURDUE PHARMACEUTICALS L.P.,
THE P.F. LABORATORIES, INC.,
Patent Owners

Case PGR2018-00048
U.S. Patent No. 9,693,961

PATENT OWNERS' NOTICE OF BANKRUPTCY FILING AND IMPOSITION OF AUTOMATIC STAY

PLEASE TAKE NOTICE that on September 15, 2019, (the "Petition Date"), Purdue Pharma L.P. and its debtor affiliates, as debtors and debtors in possession (collectively, the "Debtors"), each commenced a voluntary case (the "Chapter 11 Cases") under chapter 11 of title 11 of the United States Code (11 U.S.C. § 101 et seq.) (the "Bankruptcy Code") in the United States Bankruptcy Court for the Southern District of New York (the "Bankruptcy Court"). The Chapter 11 Cases are being jointly administered under Case No. 19-23649.

PLEASE BE ADVISED that pursuant to section 362(a) of the Bankruptcy Code (the "Automatic Stay"), the filing of a bankruptcy petition "operates as a stay, applicable to all entities," of, among other things "the commencement or continuation, including the issuance or employment of process, of a judicial, administrative, or other action or proceeding against the debtor that was or could have been commenced before the commencement of the case under [the Bankruptcy Code], or to recover a claim against the debtor that arose before the commencement of the [bankruptcy] case" and "any act to obtain possession of property of the estate or of property from the estate or to exercise control over property of the estate." 11 U.S.C. § 362(a)(1), (3).

PLEASE BE FURTHER ADVISED that any action taken against the Debtors without obtaining, from the Bankruptcy Court, relief from the Automatic Stay is void *ab initio* and may result in a finding of contempt for violation of the

Automatic Stay. The Debtors reserve and retain their statutory right to seek relief in the Bankruptcy Court from any action by Petitioner or any judgment, order, or ruling entered in violation of the Automatic Stay.

In a recent decision, Judge Saylor of the District of Massachusetts stayed a related patent litigation brought by Patent Owners against Petitioner. *See Purdue Pharma L.P. et al. v. Collegium Pharmaceutical, Inc.*, C.A. No. 15-13099, D.I. 219 (D. Mass). There, Patent Owners assert that Petitioner's extended release oxycodone product infringes certain patents, including U.S. Patent No. 9,963,961 at issue here, by the filing of Collegium's NDA and the subsequent marketing of Collegium's NDA products. After the bankruptcy filing, Purdue filed a Suggestion of Bankruptcy in the Massachusetts Court, similar to this filing. *See id.* at D.I. 218. Upon receipt, Judge Saylor issued a decision staying the action because "as a practical matter, the bankruptcy may affect the litigation in a variety of ways, including the ability or willingness of the debtor-in-possession or trustee to expend resources in support of the lawsuit and the ability of the defendant to obtain discovery and otherwise protect its rights." *Id.* at 2. Judge Saylor further stated that "where claims and counterclaims are brought in the same proceeding, there is a danger of an unfair lack of symmetry if the entire proceeding is not stayed." *Id.*

In the event the Board or any parties have questions regarding the Chapter 11 Cases, please contact counsel for the Debtors:

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Respectfully submitted,

Dated: September 24, 2019

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on September 24, 2019, a complete and entire copy of **PATENT OWNERS' BANKRUPTCY FILING AND IMPOSITION OF AUTOMATIC STAY** has been served in its entirety by e-mail on the following counsel of record for Petitioner:

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Exhibit C

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571-272-7822

Paper 45
Entered: October 2, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COLLEGIUM PHARMACEUTICAL, INC.,
Petitioner,

v.

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P.,
AND THE P.F. LABORATORIES INC.,
Patent Owner.

Case PGR2018-00048
Patent 9,693,961 B2

Before CHRISTOPHER G. PAULRAJ, JACQUELINE T. HARLOW, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge.*

ORDER

Stay of Proceeding Due to Notice of Bankruptcy Filing and Imposition of Automatic Stay
Extending One-Year Pendency for Good Cause
37 C.F.R. § 42.5; 37 C.F.R. § 42.200(c); 35 U.S.C. § 326(a)(11)

On September 24, 2019, Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. (collectively, "Patent Owner") filed a Notice of Bankruptcy and Imposition of Automatic Stay in this proceeding. *See* Paper 43 ("Notice"). As set forth in the Notice, Purdue Pharma L.P. and its debtor affiliates, as debtors and debtors in possession (collectively, the "Debtors"), each commenced a voluntary case (the "Chapter 11 Cases") under chapter 11 of title 11 of the United States Code (11 U.S.C. § 101 et seq.) in the United States Bankruptcy Court for the Southern District of New York. *Id.* at 2.

The Notice states that, pursuant to section 362(a) of the Bankruptcy Code (the "Automatic Stay"), the filing of a bankruptcy petition "operates as a stay, applicable to all entities," of, among other things "the commencement or continuation, including the issuance or employment of process, of a judicial, administrative, or other action or proceeding against the debtor that was or could have been commenced before the commencement of the case under [the Bankruptcy Code], or to recover a claim against the debtor that arose before the commencement of the [bankruptcy] case" and "any act to obtain possession of property of the estate or of property from the estate or to exercise control over property of the estate." *Id.* (citing 11 U.S.C. § 362(a)(1), (3)). The Notice further states that "any action taken against the Debtors without obtaining, from the Bankruptcy Court, relief from the Automatic Stay is void *ab initio* and may result in a finding of contempt for violation of the Automatic Stay." *Id.* at 2–3.

Following receipt of the Notice, we held a conference call on September 27, 2019, in which the judges of this panel, as well as counsel for Petitioner, Patent Owner, and Debtors participated. During the call, Patent Owner and Debtors took the position that the filing of the bankruptcy case required the Board to stay this proceeding, and that no order from the Bankruptcy Court was required for the

Automatic Stay provision to go into effect. Petitioner took the position that the Automatic Stay provision was not applicable to Board proceedings, as they are not proceedings "against the debtor," or "to obtain possession . . . or to exercise control over property of the estate." 11 U.S.C. § 362(a)(1), (3). In support, Petitioner cited to the Supreme Court's decision in *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018), and emphasized the error-correction function of AIA trial proceedings. Petitioner, however, acknowledged during the call that it could not identify any prior case in which the Automatic Stay provision was specifically determined not to apply to Board proceedings.

Under the circumstances, we determine that the disagreement as to whether the Automatic Stay provision applies to this proceeding is best addressed in the Bankruptcy Court. As such, Petitioner should seek any relief it deems appropriate from the Bankruptcy Court. The Board has taken a similar approach in prior cases involving a patent owner that has filed for bankruptcy during a trial proceeding. *See Mylan Pharms. Inc. v. Pozen Inc. and Horizon Pharma USA, Inc.*, IPR2017-01995, Paper 51 (PTAB Aug. 31, 2018) (suspending deadlines due to suggestion of bankruptcy); *Twitter, Inc. v. Youtoo Technologies, LLC*, IPR2017-00829, Paper 23 at 2 (PTAB Dec. 27, 2017) (extending deadlines to provide petitioner an opportunity to seek relief from the automatic stay (or a determination that it does not apply) by the bankruptcy court).

Our Final Written Decision in this proceeding is currently due October 4, 2019. Pursuant to 35 U.S.C. § 326(a)(11), "the final determination in any post-grant review [will] be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months." The Director has delegated the authority to extend the one-year period

to the Chief Administrative Patent Judge. *See* 37 C.F.R. § 42.200(c). In particular, 37 C.F.R. § 42.200(c) provides:

> A post-grant review proceeding shall be administered such that pendency before the Board after institution is normally no more than one year. The time can be extended by up to six months for good cause by the Chief Administrative Patent Judge.

In accordance with 37 C.F.R. § 42.200(c), the Chief Judge has determined that good cause exists to extend the one-year period for issuing a Final Written Decision here. *See* Paper 44. Accordingly, the time to administer the present proceeding is extended by up to six months. The extension will provide additional time for the Bankruptcy Court to address the applicability of the Automatic Stay provision to this proceeding.

Accordingly, it is

ORDERED that this proceeding is hereby stayed pursuant to the Automatic Stay provision of 11 U.S.C. § 362(a)(1), (3);

FURTHER ORDERED that good cause exists to extend the time of pendency in this proceeding; and

FURTHER ORDERED that this proceeding is extended by up to six months.

PGR2018-00048
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